

# UMBI

UNIVERSITY OF MARYLAND  
BIOTECHNOLOGY INSTITUTE

COLUMBUS CENTER  
701 EAST PRATT STREET, SUITE 200  
BALTIMORE, MARYLAND 21202-3101  
410.385.6305 TEL.  
410.385.6312 FAX  
WWW.UMBI.UMD.EDU

UMBI HEADQUARTERS  
9600 GUDELSKY DRIVE  
ROCKVILLE, MARYLAND 20850  
301.738.6272 TEL.  
301.738.6255 FAX

January 16, 2002

Mr. Kenneth Weber  
Partner  
Townsend and Townsend and Crew  
Two Embarcadero Center  
8<sup>th</sup> Floor  
San Francisco, CA 94111-3834

Dear Mr. Weber:

This letter is in response to your letter dated December 20, 2001 requesting my signature for the declaration (37CFR 1.63) to file a continuation to Ms. McKinney's original patent application (09/590,759). I am not signing the declaration. I feel there is a problem with the inventorship of the application.

I see no additional new claims or differences in content of claims between the parent application and this CIP. Words were added for clarification perhaps, but essentially the CIP appears to be the same application as filed by LBNL with Nancy McKinney as sole inventor. In fact, I have concerns that the claims might be subject to a double patenting rejection.

There was an LBNL/UCB inventorship investigation during the fall of 2000 as to the inventor(s) for the claims originally filed and it was determined that Nancy McKinney was the sole inventor. While employed by LBNL as Head of the Center for Environmental Biotechnology, and as the original sole PI on the Department of Energy grant award which enabled this group to come together, I organized weekly meetings to review the data obtained based on the assignments within the group consisting of Stan Goldman, Pascal Longchamp, and Nancy McKinney. I invited Terry Leighton to attend as a potential collaborator. I feel I have a very good recollection of who did what and I do not believe that any other member of the group contributed to the primer-probe (PCR) diagnostic assay for *Bacillus anthracis*, *B. globigii*, and *Clostridium perfringens* as described in the original parent patent filing with Nancy McKinney as sole inventor.

You see, the major goal of the group from the outset was to discover a spore coat protein specific to *B. anthracis*, which was my original proposal funded by DOE. PCR was employed only as a quick means to find such a protein. Prior to bringing in Nancy, no one in the group had the necessary expertise. None of the primer sets designed prior to her arrival amplified anything unique to anthrax. In fact, it was against the wishes of Dr. Leighton that Nancy chose to design primers to *saspB*. He insisted that she should focus on the 'cot', or spore coat, proteins along with Dr. Goldman.

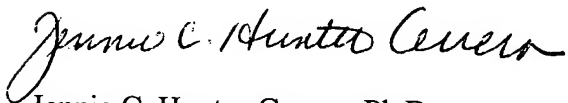
I hired Nancy McKinney because no one else in the group had her set of skills to do both basic and applied research that led to the development of the *saspB* assay. In addition, she had impeccable quality control and quality assurance skills which we needed to validate the assay and do near neighbor comparison for specificity.

Pascal Longchamp worked on identifying any enzyme activity that might be associated with spores. Stan Goldman's contribution should be evaluated by his notebook, as should all of the listed inventors. I had the original idea to look at receptors or targets that might be present on spores that could be unique and used to detect *B. anthracis* but I did not enable the invention by working in the laboratory or developing the methods to enable the discovery of a specific assay for *B. anthracis*, *B. globigii* and *C. perfringens*.

Once Nancy's initial efforts with *saspB* paid off, Dr. Leighton claimed only interest in obtaining data for constructing a phylogenetic tree of *Bacillus*. Dr. Goldman participated briefly in analysis of *saspB* then moved on to other targets. Dr. Longchamp did not participate in analysis of *saspB*. Only Nancy pursued species specific PCR assays, alone. Drs. Goldman and Longchamp were no longer even employed at LBNL when Nancy developed the anthrax specific primers and probes! And all members of the group, save myself, discouraged Nancy from pursuing this goal claiming it was not possible. She did it on her own, with my encouragement.

I do hope you can see why I have a problem with the inventorship on this CIP.

Sincerely,



Jennie C. Hunter-Cevera, Ph.D.  
President, UMBI